

DAIDS Bethesda, MD USA	POLICY	No.: DWD-POL-CL-05.00
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	Approval Date: 14 JUL 06 Effective Date: 01 NOV 06	Replaces: None

1.0 PURPOSE

The purpose of this policy is to identify required content in a clinical research site Manual of Operational Procedures (MOP) and provide guidance to research personnel in its development and maintenance.

2.0 SCOPE

This policy applies to all Clinical Research Sites conducting DAIDS funded and/or sponsored therapeutic, vaccine, or prevention clinical trials both domestic and internationally.

3.0 BACKGROUND

A MOP serves as a reference document for clinical trial operations at a site. The MOP is the entire project team's guide for the complete operational management of a clinical research site including administrative and management activities, regulatory affairs, and study implementation. It may also serve as a training tool for protocol initiation activities.

MOP are developed and utilized to ensure that at all time the study is conducted in compliance with all applicable regulation. Clinical trials funded and/or sponsored by DAIDS must be in compliance with applicable U.S. Code of Federal Regulations, standards for good clinical practice (GCP), NIH and DAIDS, NIAID policy and procedures and any applicable local laws, regulations or institutional policy and procedures.

4.0 DEFINITIONS

GCP – Good Clinical Practice

GCLP – Good Clinical Laboratory Practice

IATA – International Air Transport Association training/certification for shipping dangerous goods

For additional definitions see DAIDS Glossary.

5.0 RESPONSIBILITIES

The Principal Investigator or designee is responsible for ensuring that the MOP is developed and sufficiently detailed to guide study activities, is revised as necessary to incorporate changes to procedures, and that all available copies of the MOP contain the most current information.

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6.0 POLICY

- All policy and Standard Operating Procedures included in the MOP must comply with applicable U.S. Code of Federal Regulations, standards for good clinical practice (GCP), NIH and DAIDS, NIAID policy and procedures and any applicable local laws, regulations or institutional policy and procedures.
- The MOP must be distributed to all Clinical research site staff prior to the initiation of the project. Clinical research site staff must have ready access at all times to the MOP either in electronic format or hard (paper) copy.
- Clinical research site staff must use the MOP as an aid for initiating and implementing the clinical study.
- A core set of Standard Operating Procedures (SOPs) must be in place **prior to** the initiation of any DAIDS sponsored and/or funded clinical research. These required SOPs are listed in bold type in Appendix 1: Sample Table of Contents. The contents of the resulting MOP may be in any order.
- Other SOPs should be developed as applicable to the clinical research, but are not required to be in place at the site prior to initiation of the project.
- When procedures change and revisions to the MOP are necessary, a numerical identifier must be used to create and control all versions. A copy of each non-current version of the MOP must be retained and archived.
- The MOP must be available to DAIDS staff or DAIDS designated representatives for inspection upon request.

7.0 REFERENCES

U.S. Code of Federal Regulations: 45 CFR 46, 45 CFR 46, Subpart D, 21 CFR 50, 21 CFR 56, 21 CFR 312, and 21 CFR 11

FDA Information Sheets, Guidance for IRBs and Investigators 1998 Update

International Conference on Harmonisation (ICH), Guidance for Industry, E6 Good Clinical Practice

DAIDS Data Management Requirements for Data Management Facilities

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8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at:

NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:

<http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Default.htm>

The signed original is maintained in the OPCRO policy office.

10.0 CHANGE SUMMARY

Version #	Date	Replaces	Date of Revision	Rationale for Revision/Retirement
1.0	14 JUL 06	N/A	N/A	N/A


11.0 APPENDICES

Appendix 1 – Sample Table of Contents

Appendix 2 – Required Site SOPs

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12.0 APPROVAL

	Signature	Program/Branch	Date
Authorized By:	 Richard Hafner, MD Director	Office for Policy in Clinical Research Operations	July 14, 2006